Alaska Medicaid

KALYDECO™(ivacaftor)

Available 150mg tablet

INDICATIONS and USAGE:

"KALYDECO is classified as a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator. KALYDECO is indicated for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have a G551D mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the G551D mutation.
Limitations of Use
KALYDECO is not effective in patients with CF who are homozygous for the F508del mutation in the CFTR gene and has not been studied in other populations of patients with CF. "[1]

Criteria for Approval:

1. Diagnosis of Cystic Fibrosis; **AND**
2. Confirmed G551D mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene from an FDA-cleared CF mutation test; **AND**
3. Recipient is 6 years of age or older.

Length of Authorization:

1. Coverage may be approved for 2 months.
2. *Re-authorization*, documentation of clinical improvement may be approved for 10 months

Dispensing Limit:

1. The dispensing limit is a 30 day supply of medication with a **Quantity Limit** of 2 doses per day

References:

[1] Kalydeco™ package insert is available at: <http://pi.vrtx.com/files/uspi_ivacaftor.pdf >
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